BIO-TEK INSTRUMENTS INC.

M/N 10 SAFETY ACCESSORY SYSTEM

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BIO-TEK INSTRUMENTS INC.

INSTRUCTION MANUAL

MODEL 10 SAFETY ACCESSORY SYSTEM

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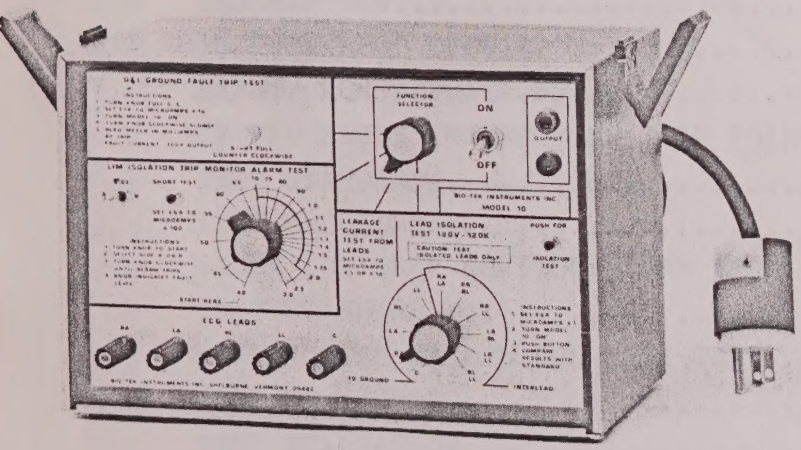

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MODEL 10 INSTRUCTION MANUAL

1.0 INTRODUCTION

The Model 10 Accessory System, in conjunction with an Electrical Safety Analyzer (ESA), accomplishes the following functions:

A. Tests ground fault interrupt trip level;

B. Tests isolation monitor trip point;

C. Measures leakage current from EKG leads;

D. Measures isolation of isolated EKG leads using 120 volts as the stress voltage.

All of the above is accomplished easily as a result of modern engineering design techniques. The Model 10 can be used with any Electrical Safety Analyzer with microampere ranges from 10 to 1000 microamps.

2.0 UNPACKING INSTRUCTIONS

Unpack the shipping carton. Check contents of the shipping carton for the following:

A. Model 10 ESA Accessory System;

B. Five (5) banana jack adapters with alligator clips;

C. Two Instruction Manuals.

3.0 DESCRIPTION

The Model 10 is packaged in a blue aluminum case with all functions located on the front panel. Line fuses, spare fuse and power cord are located on the back panel.

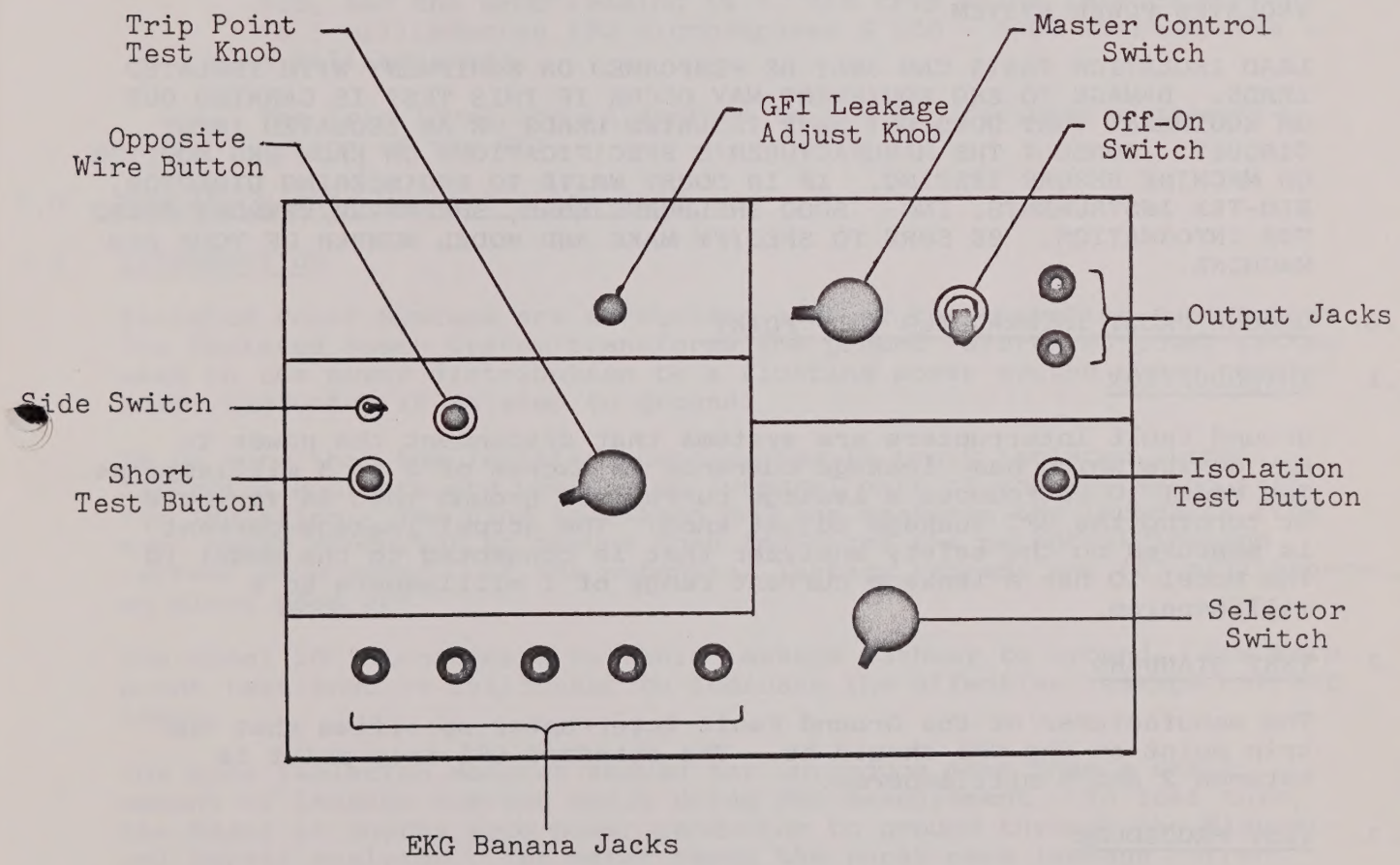
The front panel is divided up into 4 major sections. The Master Control Section is located on the upper right hand corner. The red and black jacks labeled "Output" are used to connect the Model 10 to a safety analyzer. The OFF-ON switch completely disconnects both the hot and neutral from the circuitry. The master control switch selects the function for testing. The four position switch rotates to each function area.

The Ground Fault Interrupt (GFI) Test System is located in the upper left corner. The leakage adjust knob puts a variable leakage from hot power conductor to ground.

The Line Isolation Monitor (LIM) Test System is located in the middle left. The side switch selects the power conductor that is to be tested. The short test button connects the power conductor indicated on the side toggle switch directly to the safety analyzer which is connected to ground. The opposite wire button connects the safety analyzer between ground and the opposite power conductor to see what the hazard index is. The trip point test knob is calibrated to show the effective hazard index that the Model 10 is introducing into the system. The variable trip point test knob introduces a single sided fault from the power conductor to ground.

The EKG Lead Leakage Current Test System is located on the bottom of the front panel. The five (5) banana jacks connect with the EKG leads. The selector switch connects each lead to the safety analyzer as indicated on the dial.

The EKG Lead Isolation Test System is located on the bottom right side. The isolation test button connects the lead indicated on the selector switch to 120 volts through 120,000 ohm resistance and the safety analyzer. The safety analyzer indicates the current flowing into the lead directly.



MODEL 10 FRONT PANEL LAYOUT

4.0 ASSEMBLY FOR OPERATION

A. The Model 10 can be mechanically attached to the Model 250M or 150M Electrical Safety Analyzer by the plastic mounting clips on the top of both sides.

B. Connect the input leads of the ESA to the output jacks on the upper right of the Model 10, red to red, black to black.

5.0 SAFETY CONSIDERATIONS: PLEASE READ BEFORE USE!

THE MODEL 10 CHASSIS IS UNGROUNDED AND FLOATING. THE GROUND WIRE OF THE MODEL 10 POWER CORD IS USED TO CARRY FAULT CURRENTS IN EXCESS OF 100 MICROAMPERES.

IT IS RECOMMENDED THAT THE CHASSIS OF THE MODEL 10 BE CONNECTED TO THE CHASSIS OF THE ELECTRICAL SAFETY ANALYZER. A GROUND JACK AND GROUND WIRE IS PROVIDED ON THE BACK PANEL OF THE MODEL 10.

IF THE MODEL 10 IS USED IN CONJUNCTION WITH THE MODEL 250M OR 250MA ELECTRICAL SAFETY ANALYZER, THE CHASSIS SHOULD BE CONNECTED USING THE GROUND JACK ON THE BACK PANEL OF THE MODEL 250M/250MA.

THE MODEL 10 CANNOT BE USED IN ANY ROOM WHERE A PATIENT IS LOCATED.

THE MODEL 10 MUST BE USED WITH A PREVIOSULY TESTED OUTLET. THE OUTLET MUST HAVE PROPER POLARITY AND BE GROUNDED UNLESS IT IS AN ISOLATED POWER SYSTEM.

LEAD ISOLATION TESTS CAN ONLY BE PERFORMED ON EQUIPMENT WITH ISOLATED LEADS. DAMAGE TO EKG EQUIPMENT MAY OCCUR IF THIS TEST IS CARRIED OUT ON EQUIPMENT THAT DOES NOT HAVE ISOLATED LEADS OR AN ISOLATED INPUT CIRCUIT. CONSULT THE MANUFACTURER'S SPECIFICATIONS ON EACH EKG MONITOR OR MACHINE BEFORE TESTING. IF IN DOUBT WRITE TO ENGINEERING DIRECTOR, BIO-TEK INSTRUMENTS, INC., 5000 SHELBURNE ROAD, SHELBURNE, VERMONT 05482 FOR INFORMATION. BE SURE TO SPECIFY MAKE AND MODEL NUMBER OF YOUR EKG MACHINE.

6.0 GROUND FAULT INTERRUPTER TRIP POINT

6.1 INTRODUCTION

Ground Fault Interrupters are systems that disconnect the power to any device which has leakage currents in excess of 2 to 5 milliamperes. The Model 10 introduces a leakage current to ground that is variable by turning the GFI leakage adjust knob. The actual leakage current is measured on the safety analyzer that is connected to the Model 10. The Model 10 has a leakage current range of 1 milliampere to 6 milliamperes.

6.2 TEST STANDARD

The manufacturer of the Ground Fault Interrupter specifies what the trip point on the GFI should be. The standard GFI trip point is between 2 and 5 milliamperes.

6.3 TEST PROCEDURE

A. Put the Model 10 OFF-ON switch on OFF.

B. Connect the Model 10 power cord to a receptacle connected to the GFI under test.

C. Turn the master control switch to its most clockwise position pointing to the GFI test system.

D. Turn the GFI leakage adjust knob all the way counter clockwise.

E. Put the Electrical Safety Analyzer on to microamps X10 (a range that should go to at least 60 microamperes.)

F. Turn the Model 10 ON.

G. Turn the GFI leakage adjust knob slowly clockwise while

watching the meterface of the electrical safety analyzer. The meter reading will increase and indicate the current going into the ground wire until the GFI trips at which time the reading will go to zero.

H. The trip current is the maximum reading the meter attains before the GFI trips off.

I. The meter reads directly in milliamperes. The output current into the electrical safety analyzer is equal to 1/100 of the current going to ground, thus the ground leakage current is equal to 100 times the current measured on the electrical safety analyzer. For example: with the ESA set on microamps X10, and the meter reading is 5, the trip point leakage current is 5 milliamperes (50 microamperes X 100 = 5000 microamperes = 5 milliamperes).

J. The trip level should conform to the manufacturer's specification of the GFI.

7.0 ISOLATION TRIP MONITOR ALARM TEST

7.1 INTRODUCTION

Isolated Power Systems are a required part of the operating room suites. The Isolated Power System transforms the ground referenced power system used in the power distribution to a floating power system where neither power conductor is related to ground.

To be sure that the isolated power system is truly isolated, Line Isolation Monitors are used as an integral part of the system to test for isolation. The Line Isolation Monitor measures the impedance from each power conductor to ground then indicates the potential leakage current on a meter. If the potential leakage exceeds two (2) milliamperes, an alarm goes off.

The Model 10 introduces a variable leakage pathway to ground. The trip point test knob is calibrated to indicate the effective leakage current level.

The Line Isolation Monitor should not introduce more than a small amount of leakage current while doing the measurement. To test this, the Model 10 shorts each power conductor to ground through the Electrical Safety Analyzer. The meter reads the worst case leakage current assuming someone put his finger on each power conductor.

The opposite wire button verifies what the trip point test knob indicates. The trip point test knob introduces an impedance from the power conductor selected by the side switch to ground. This creates a single fault between one power conductor and ground. The knob indicates the leakage current that could flow if someone came in contact with the opposite power conductor. The opposite wire button connnects the Electrical Safety Analyzer to the opposite conductor to measure the leakage current at the point the alarm trips.

7.2 TEST STANDARD

Line Isolation Monitors according to the NFPA 56A should trip when the potential leakage current is between .7 and 2 milliamperes. The

short circuit leakage, when nothing except the Line Isolation Monitor is connected to the circuit, should be less than 1 milliampere.

7.3 ACCESSORIES NEEDED FOR THIS TEST

All Isolated Power Systems in operating rooms use special locking connectors to minimize sparks. To connect the Model 10 to the locking connectors in the operating room, an adapter must be used. The Model NF23/1 is a connector for one type of twist locking connector.

ADAPTER CORD NF-23-1

The NF23/1 has a male explosion-proof twist lock on one end with a regular female three-prong receptacle at the other.

The male explosion-proof twist lock is inserted into the wall mounted, explosion-proof, twist lock receptacle leaving the female three-prong receptacle available so that the test may be conducted.

7.4 TEST PROCEDURE

A. Connect the Model 10 to a receptacle powered by the Isolated Power System using an adapter.

B. Be sure the Model 10 is OFF.

C. Turn the master control switch to the Line Isolation Monitor trip point test.

D. Put the Electrical Safety Analyzer on microamps X1.

E. Put the side switch on "A".

F. Turn the trip point test knob fully counter clockwise.

G. Turn the Model 10 ON.

H. Slowly rotate the trip point test knob until the Line Isolation Monitor alarm goes off.

I. Push the opposite wire button. The Electrical Safety Analyzer will read 1/100 of the current flowing to ground from the power conductor. So the actual leakage current is the Electrical Safety Analyzer reading times 100. (Example: if the meter reads 10 microamps, the actual opposite wire leakage is 10 X 100 or 1000 microamperes = 1 milliampere).

J. Turn the Electrical Safety Analyzer to microamps X100.

K. Push the short test button. The meter should read less than 1 milliampere if there is no other device operating from the circuit. This connect power conductor "A" to ground through the Electrical Safety Analyzer.

L. Repeat steps A through K with the side switch on "B".

7.5 TEST EVALUATION

The leakage measured on the opposite wire test of 7.4 "I" is the actual hazard current flowing at the trip point of the Line Isolation Monitor. The meter should read close to the leakage current indicated on the Trip Point Test Knob but no more than the sum of the Short Test Button leakage of step 7.4 "K" and the Trip Point Test Knob current indicated in step 7.4 "I".

8.0 EKG LEAD CURRENT TESTING

8.1 INTRODUCTION

EKG lead leakage current measurement is done efficiently using the Model 10 as a master switch box. The EKG lead leakage current to ground and all the interlead combinations are accomplished in 15 seconds. The Model 10 switches each lead appropriately to the electrical safety analyzer.

8.2 TEST STANDARDS

The recommended test standard is as follows:

10 microamperes maximum for equipment with isolated lead input

50 microamperes maximum for equipment with non-isolated lead input

3 TEST PROCEDURE

A. Be sure Model 10 in on OFF position.

B. Turn the Function selector Switch to the line leading to leakage current tests from leads.

C. Connect the ESA and the Model 10 directly to a previously tested and approved receptacle.

D. Plug the EKG equipment into the ESA (e.g. Model 250M or 150M) or into a wall receptacle.

E. Connect the EKG leads to the Model 10 jacks directly or using the alligator clip adapters.

F. Turn the Electrical Safety Analyzer to microamps X1.

G. Turn the EKG machine ON.

H. Turn lead switch to all positions and combinations noting the leakage current reading on each position (e.g. C, RA, LA, RL and LL).

I. Compare the results with the standards adopted by the facility.

J. Reverse the polarity on the power to the EKG machine by turning a switch on the Model 250M or 150M.

K. Repeat steps G and H.

L. Break the ground of the power going to the EKG machine by turning the ground switch on the Model 250M or 150M.

M. Repeat steps G and H.

N. Return the polarity switch to NORMAL on the 250M or 150M.

O. Repeat steps G and H.

NOTE: The polarity changing and ground breaking can be accomplished using a NEMA Adapter.

9.0 LEAD ISOLATION TEST

9.1 INTRODUCTION

As a safety feature, many new EKG monitors and machines have isolated input systems. The isolated input creates a safety measure by providing no connection to ground through the EKG leads. To test the level of isolation, a grounded power source of 120 volts through a limiting resistor of 120,000 ohms is connected to each lead. The Electrical Safety Analyzer is connected in the circuit and actually measures the current leakage to ground through each lead.

CAUTION: This test can be performed only on EKG equipment that has isolated leads or isolated input. Please refer to the manufacturer's manual to determine if the EKG equipment is isolated or not. If not: DO NOT DO THIS TEST.

9.2 TEST STANDARD

The recommended maximum for leakage current through isolated leads is 10 microamperes.

9.3 TEST PROCEDURE

A. Plug the ESA (250M or 150M) and the Model 10 directly into a previously tested receptacle.

B. Connect the EKG equipment leads to the jacks on the Model 10 directly or using alligator clip adapters.

C. Plug the EKG machine into the Model 250M or directly into the wall and turn it ON.

E. Turn the Model 10 ON.

F. Set the ESA to microamperes X1.

G. Push the isolation test button.

H. Compare the results with standards adopated by the facility and the manufacturer's specifications.

I. Turn the lead knob to each single labeled position (C, RA, LA, RL, LL) and push the test button and compare the meter reading with the standards. For the single designations (i.e. RA) the reading represents isolation to ground; for the double designations there is no reading.

J. This test put 120 volts through 120,000 ohms from ground to each lead thorugh the ESA. The ESA is measuring the actual current going into the leads and thus, the effectiveness of the isolation.

K. The interlead positions of the lead switch will not read anything while the function selector is in lead isolation position. The lead isolation measures only isolation to ground for each lead.

10.0 SPECIFICATIONS

GFI Test: Current range 1-6 ma

LIM: Current range .4 ma to 3.0 ma ±10%

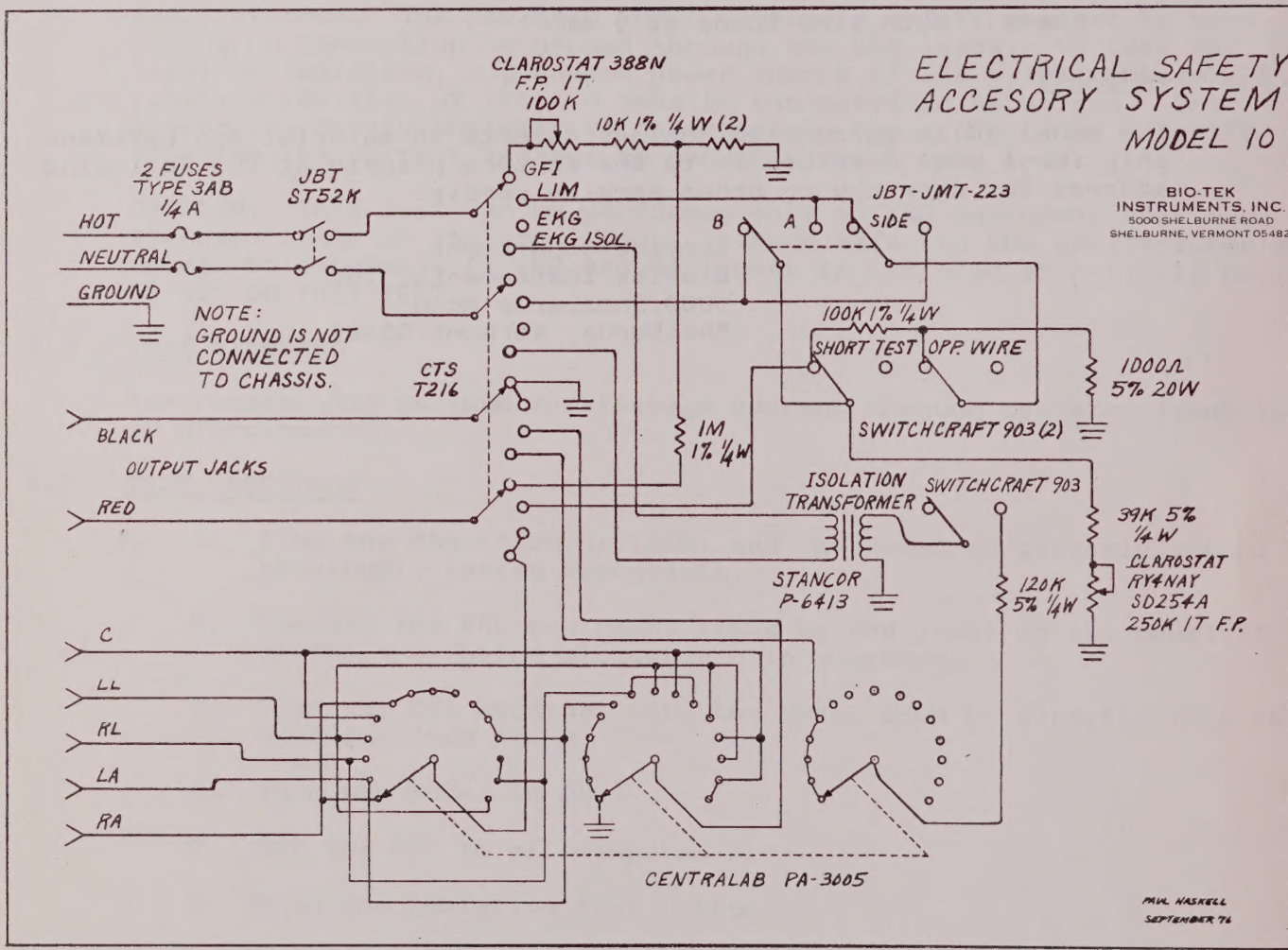
Fuses: Both line fused at $\frac{1}{4}$ amp

11.0 WARRANTY

The Model 10 is warrantied against defects in material and workmanship for 1 year. Return it to the factory prepaid at the following address for warranty or other service repair:

Service Department
Bio-Tek Instruments, Inc.
5000 Shelburne Road
Shelburne, Vermont 05482

12.0 SCHEMATIC DIAGRAM



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